# FORTEO®1 (teriparatide)
# TYMLOS®1 (abaloparatide)

## UTILIZATION MANAGEMENT CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS:</th>
<th>Recombinant Human Parathyroid Hormone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BRAND (generic) NAMES:</strong></td>
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<tr>
<td>• Forteo (teriparatide) Multi-dose prefilled delivery device (pen) containing 28 daily dose of 20 mcg</td>
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</tr>
<tr>
<td>• Tymlos (abaloparatide) Multi-dose prefilled delivery device (pen) containing 30 daily dose of 80 mcg</td>
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</tbody>
</table>

## FDA-APPROVED INDICATIONS:

Forteo is recombinant human parathyroid hormone analog (1-34), [rhPTH(1-34)] indicated for:
- Treatment of postmenopausal women with osteoporosis at high risk for fracture,
- Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture,
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture.

TYMLOS is a human parathyroid hormone related peptide [PTHrP(1-34)] analog indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture.

## COVERAGE AUTHORIZATION CRITERIA:

Forteo (teriparatide) or Tymlos (abaloparatide) may be eligible for coverage when the following criteria are met:

1. The patient is ≥18 years of age or older; **AND**
2. The patient has a confirmed diagnosis of osteoporosis defined as one of the following:
   a. a history of vertebral fracture(s) or low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] within the past 5 year; **OR**
   b. The patient has a T-score that is -2.5 or lower; **AND**
      i. The patient has previously been treated with a bisphosphonate or selective estrogen receptor modulator (SERM) and experienced a therapeutic failure or inadequate response; **OR**
      ii. The patient is unable to receive a bisphosphonate or SERM due to a contraindication/hypersensitivity; **AND**
3. The patient will not be receiving concurrent treatment with a bisphosphonate and SERM; AND
4. The patient does not have any of the following conditions where use of these medications would not be recommended:
   a. Hypercalcemia
   b. Paget’s disease
   c. Prior radiation therapy involving the skeleton
   d. Bone metastases or history of skeletal malignancies
   e. Metabolic bone disease other than osteoporosis; AND
5. The duration of treatment will be/is no longer than 2 years during a patient’s lifetime; AND
6. The use of Tymlos (abaloparatide) is restricted to postmenopausal women; AND
7. Non-Formulary Exception criteria applies on formularies which exclude requested product(s). Satisfactory completion of criteria points (above) may satisfy some, or all, portions of the Non-Formulary Exception Criteria. This criteria is summarized as:
   a. Request must be for an FDA approved indication; AND
   b. Patient must have a trial and failure of up to TWO formulary medications or a clinical contraindication/intolerance to those medications not tried.

Duration of approval: 2 years (730 days)

QUANTITY LIMIT EXCEPTION CRITERIA

Quantities and/or courses of therapy above the program set limit for Forteo and Tymlos may be eligible for coverage when the following are met:

1. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer’s product insert; OR
2. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer’s product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

<table>
<thead>
<tr>
<th>Medication Name/Strength</th>
<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td>Forteo 600 mcg/2.4 mL</td>
<td>2.4 mL every 28 days</td>
</tr>
<tr>
<td>Tymlos 3120 mcg/1.56 mL</td>
<td>1.56 mL (1 pen) every 30 days</td>
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</tbody>
</table>

REFERENCES:


POLICY IMPLEMENTATION/UPDATE INFORMATION
May 2017: New to market Tymlos added to policy.

January 2017: Reviewed for ASO Net Results; clarified definition of osteoporosis.

January 2016: Added a Quantity Limit to the criteria.

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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)

• Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

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• You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office is available to help you.

• You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights.

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MLHOUO: Èka kànt Tàhtóshì thàrfaghàri, ëfan xàmdàthàta màstàalàtghàri thàno tomlaàlìb gëmtàr, ëfan xàmdàthàta màstàalàtghàri thàno tomlaàlìb gëmtàr. ÀnÜshí bar bëm.


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